

Serial No. 09/777,091

PATENT

COMPLETE SET OF CLAIMS

1        1. (Currently Amended) An implantable valve for a bodily passage of  
2        tubular shape, comprising:  
3                a self-expanding support frame configured for expansion to  
4        conform to a wall of the bodily passage, said support frame having a  
5        plurality of bends, said plurality of bends configured to provide outward  
6        radial force for expansion of said self-expanding frame to anchor the  
7        implantable valve to the wall of the bodily passage, said support frame  
8        when expanded providing a plurality of side elements each defining a  
9        path extending at least partially longitudinally along the wall and at least  
10       partially circumferentially around the wall,  
11               a plurality of leaflets, each leaflet thereof having a body  
12       extending from a wall-engaging outer edge to an inner edge proximate  
13       a corresponding inner edge of at least one other leaflet of the plurality of  
14       leaflets,  
15               the inner edges of said plurality of leaflets cooperable to define  
16       an opening therebetween to permit fluid flow in a first direction along the  
17       bodily passage, and further cooperable to engage each other sufficiently  
18       to restrict fluid flow in a second direction opposing the first direction,  
19               the outer edge of each one of the plurality of leaflets attached  
20       along one side element of said plurality of side elements and thereby  
21       adapted to sealingly engage the wall of the bodily passage in said path  
22       extending at least partially longitudinally and at least partially  
23       circumferentially such that the leaflet extends along said bodily passage  
24       away from the inner edges in said second direction, each of said leaflets  
25       thereby forming a curved structure for trapping fluid between the leaflets  
26       and the inner wall of the bodily passage in response to fluid flow in said  
27       second direction so as to cause said inner edges of said leaflets to  
28       engage one another sufficiently to restrict fluid flow in said second  
29       direction.

Serial No. 09/777,091

PATENT

1      2. (Currently Amended) The ~~vascular~~ implantable valve of claim 1,  
2      wherein at least a portion of the body of the leaflet being flexible at least  
3      proximate the ~~free~~ inner edge thereof.

1      3. (Canceled)

1      4. (Currently Amended) The implantable valve of claim 3 1 wherein the  
2      outer edges of the plurality of leaflets include overhanging material, the  
3      overhanging material extending beyond the frame to which the plurality  
4      of leaflets are attached.

1      5. (Currently Amended) The implantable valve of claim 3 1 wherein said  
2      frame comprises wire to and around which the bodies of the leaflets are  
3      secured.

1      6. (Previously Amended) The implantable valve of claim 1 wherein the  
2      plurality of leaflets includes two leaflets such that when the frame is  
3      substantially flattened, it assumes a diamond shape with the inner edges  
4      of the two leaflets defining a slit therebetween.

1      7. (Original) The implantable valve of claim 3 wherein the body and the  
2      frame of each leaflet comprises an integral, one-piece member.

1      8. (Original) The implantable valve of claim 1 wherein said integral, one-  
2      piece member is molded into a generally flat shape.

1      9. (Original) The implantable valve of claim 7 wherein said integral, one-  
2      piece member is molded into a serpentine shape.

Serial No. 09/777,091

PATENT

1 10. (Amended) The implantable valve of claim 1 wherein the plurality of  
2 leaflets comprises an extracellular collagen matrix.

1 11. (Original) The implantable valve of claim 6 10 wherein the  
2 extracellular collagen matrix includes small intestinal submucosa.

1 12. (Original) The implantable valve of claim 1 comprising two leaflets.

1 13. (Original) The implantable valve of claim 1 wherein the frame is  
2 adapted to assume a plurality of configurations, the plurality of  
3 configurations includes a generally flat configuration, whereby the frame  
4 in the generally flat configuration is generally diamond-shaped.

1 14. (Cancelled)

1 15. (Original) The implantable valve of claim 1 further including at least  
2 one barb to anchor the implantable valve to the wall of the bodily  
3 passage.

1 16. (Original) The implantable valve of Claim 15 wherein the at least one  
2 barb is integral projection extending from the frame.

1 17 - 54 (Canceled)

1 55. (Currently Amended) An Implantable valve for a bodily passage of  
2 tubular shape, comprising:  
3 a support frame configured for expansion to conform to a wall  
4 of the bodily passage, said support frame when expanded providing a  
5 plurality of side elements each defining a path extending at least partially  
6 longitudinally along the wall and at least partially circumferentially  
7 around the wall,

Serial No. 09/777,091

PATENT

8 a plurality of leaflets comprising an extracellular collagen  
9 matrix material, each leaflet thereof having a body extending from a  
10 wall-engaging outer edge to an inner edge proximate a corresponding  
11 inner edge of at least one other leaflet of the plurality of leaflets,  
12 the inner edges of said plurality of leaflets cooperable to define  
13 an opening therebetween to permit fluid flow in a first direction along the  
14 bodily passage, and further cooperable to engage each other sufficiently  
15 to restrict fluid flow in a second direction opposing the first direction,  
16 the outer edge of each one of the plurality of leaflets attached  
17 along one side element of said plurality of side elements and thereby  
18 adapted to directly engage the wall of the bodily passage therearound  
19 and provide ingrowth of adjacent native tissue into the extracellular  
collagen matrix material.

1 56. (New) The implantable valve of claim 55 wherein the collagen matrix  
2 material comprises submucosal tissue.

1 57. (New) The implantable valve of claim 55 wherein the collagen matrix  
2 material comprises small intestinal submucosa.

1 58. (New) An implantable valve for a bodily passage of tubular shape,  
2 comprising:

3 a frame that includes a plurality of legs, each of the legs  
4 originating from a pair of bends located about a first end of the  
5 implantable valve, and extending in an opposite direction therefrom,  
6 each of the plurality of legs terminating at a second end of the  
7 implantable valve opposite the first end such that the plurality of legs  
8 generally assume a serpentine configuration along the circumference of  
9 a bodily passage when situated therein,

10 a plurality of leaflets, each leaflet comprising a covering that  
11 includes one or more flexible materials, the leaflet including a body that

Serial No. 09/777,091

PATENT

12 comprises a wall-engaging outer edge and an inner edge, the outer edge  
13 at least partially attached to, and reinforced by one of the plurality of  
14 legs, the outer edge and the associated leg adapted to sealingly engage  
15 the inner wall of the bodily passage,

16 wherein the body of the leaflet extends inward from the wall  
17 of the bodily passage and extending toward the first end of the  
18 implantable valve where it terminates at the inner edge, the body and  
19 inner edge traversing the lumen of the bodily passage when situated  
20 therein and being configured such that the leaflet is cooperable with at  
21 least one other leaflet to define an opening that permits positive flow of  
22 fluid therethrough in a first direction, while the plurality of leaflets are  
23 further adapted to trap between the leaflets and the inner wall of the  
24 bodily passage fluid flowing in a second direction opposite the first  
25 direction and seal against one another to restrict fluid flow in said second  
26 direction; and

27 wherein the frame is adapted to assume a plurality of  
28 configurations, a first configuration of the plurality of configurations  
29 being a generally flat plane.

*said fluid*

1 59. (New) An implantable valve for a bodily passage of tubular shape,  
2 comprising:

3 a frame that includes a plurality of legs, each of the legs  
4 originating from a pair of bends located about a first end of the  
5 implantable valve, and extending in an opposite direction therefrom,  
6 each of the plurality of legs terminating at a second end of the  
7 implantable valve opposite the first end such that the plurality of legs  
8 generally assume a serpentine configuration along the circumference of  
9 a bodily passage when situated therein,

10 a plurality of leaflets, each leaflet comprising a covering that  
11 includes one or more flexible materials, the leaflet including a body that  
12 comprises a wall-engaging outer edge and an inner edge, the outer edge

Serial No. 09/777,091

PATENT

13 at least partially attached to, and reinforced by one of the plurality of  
14 legs, the outer edge and the associated leg adapted to sealingly engage  
15 the inner wall of the bodily passage,

16 wherein the body of the leaflet extends inward from the wall  
17 of the bodily passage and extending toward the first end of the  
18 implantable valve where it terminates at the inner edge, the body and  
19 inner edge traversing the lumen of the bodily passage when situated  
20 therein and being configured such that the leaflet is cooperable with at  
21 least one other leaflet to define an opening that permits positive flow of  
22 fluid therethrough in a first direction, while the plurality of leaflets are  
23 further adapted to trap between the leaflets and the inner wall of the  
24 bodily passage fluid flowing in a second direction opposite the first  
25 direction and seal against one another to restrict fluid flow in said second  
26 direction; and

*said fluid*

27 wherein the frame is adapted to assume a plurality of  
28 configurations, a first configuration of the plurality of configurations  
29 being a generally flat plane; and

30 wherein the covering includes two leaflets such that when the  
31 frame in the generally flat configuration generally assumes a diamond  
32 shape with the inner edges of the two leaflets defining a slit  
33 therebetween.

1 60. (New) A valve prosthesis for an implantation in blood vessel,  
2 comprising:

3 a support frame including a plurality of interconnected sides,  
4 the support frame being collapsible into a first configuration for  
5 intravascular delivery into the bodily passage and expandable into a  
6 second configuration for implantation therein;

7 a plurality of leaflets, each leaflet having an inner edge and an  
8 outer edge;

*expandable*

*new - 21 - claim*

Serial No. 09/777,091

PATENT

112 <sup>and</sup> a. b.

1 wherein the inner edges of the plurality of leaflets are  
2 cooperable with one another to permit blood flow in a first direction  
3 within the vein, while restricting blood flow in a second direction  
4 opposite the first direction; and

5 wherein the outer edge of each of the plurality of leaflets is  
6 attached to at least one of the plurality of interconnected side elements  
7 such that the plurality of outer edges engage the walls of the bodily  
8 passage and collectively form a seal thereagainst along a pathway  
9 defined by the plurality of interconnected side elements.

1 61. (New) The valve prosthesis of claim 55 wherein plurality leaflets  
2 comprise a bioremodelable material.

support ???